

# Current Overview of COVID Vaccines as of 10<sup>th</sup> June 2021

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# My background – Who I am

No COI

Family physician in Japan for 18 years

- Outpatient and home care based

Special interests to **Vaccines** in the latter half of FP career

- As well as to **Travel medicine**; CTH by ISTM in 2008

Airport Quarantine Officer for 4 years

- Chubu Airport Quarantine Office

Planning xxx after finishing DTM&H...

# My works and activities associated with COVID-19 and COVID vaccines

The screenshot shows the CareNet website. At the top, there's a banner for a "COVID-19対策Webセミナー" (COVID-19 Countermeasure Web Seminar) featuring Dr. Moriya Akinari. Below this, there's a section titled "ワクチン新型コロナウィルスと検疫【今、知っておきたいワクチンの話】総論 第5回" (Vaccine, New Coronavirus and Quarantine [Today's Vaccine Talk] General Overview, Part 5). The main part of the screenshot is a grid of 19 experts, each with a photo and name, under the heading "COVID-19-19人の専門家からのアップデート" (COVID-19 Update from 19 Specialists). The experts are listed as follows:

- 9. 臨床像 忽那 賢志 (Clinical Image: Kenji Inoue)
- 10. 重症例 川名 明彦 (Severe Cases: Akihiko Kawasaki)
- 11. COVID-19の薬物治療 土井 洋平 (COVID-19 Drug Treatment: Yohei Doi)
- 12. 医療施設におけるCOVID-19の対策のポリシー (後編) 堀 賢 (COVID-19 Countermeasure Policy in Medical Facilities (Part 2): Kenji Hori)
- 13. COVID-19と小児 森内 浩幸 (COVID-19 and Children: Hiroyuki Moriuchi)
- 14. COVID-19と妊婦 池田 智明 (COVID-19 and Pregnant Women: Tomonori Ikeda)
- 15. クラスター班の活動 押谷 仁 (Cluster Unit Activities: Hitoshi Oshiyama)
- 16. 流行予測 西浦 博 (Epidemic Prediction: Hiroshi Nishimura)
- 17. グループ・ダイアモンド・グリーンセス号船橋 山岸 拓也 (Group/Diamond/Green Seas Ship: Hiroshi Yamakoshi)
- 18. 検疫所での対応 守屋 章成 (Quarantine Station Response: Akinari Moriya)
- 19. 武漢からの帰国者対応 堀川 直登 (Response to Returnees from Wuhan: Naotaka Horikawa)

At the bottom right of the grid, there's a section for "コーディネーター 学校保健のインパル 守屋 章成" (Coordinator: School Health Impulse Akinari Moriya).

The screenshot shows a presentation slide titled "PCR検査を理解するために" (To Understand PCR Testing). The slide is divided into sections: "Overview", "PCR検査を理解するために", "Summary", and "PCR検査の原理". The "Summary" section lists key points about PCR testing, and the "PCR検査の原理" section explains the process. Below the slide, there's a YouTube video thumbnail featuring Dr. Moriya Akinari and several dogs.

# Today's talk: "non-systematic review" of medical literatures of COVID vaccines

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Around **100 original articles/correspondences** relevant to COVID vaccines reviewed

- **1-3 new medical articles** being added **every week** since December 2020

NOTICE: All of today's discussions are **subject to change** according to the progresses of medical researches and expansion of COVID vaccine uptake all over the world


- **Keep your eyes on every new article!**

1. **Classification** of COVID vaccines
2. **Vaccine efficacy/effectiveness** of COVID vaccines
3. **Reactogenicity** and **anaphylaxis** due to COVID vaccines
4. **Unexpected severe adverse events**/ how to interpret reported adverse events
5. What to consider and how to decide to vaccinate **specific subpopulations**
6. **Will COVID vaccines make us free** from facemask and life restrictions?

# 1. Classification of COVID vaccines

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One of world's oldest COVAC bottle on Mt. Unzen,  settled far before the pandemic (taken on 6<sup>th</sup> June 2021)



# 1. COVID vaccine development – **spike (S) protein** is the target antigen

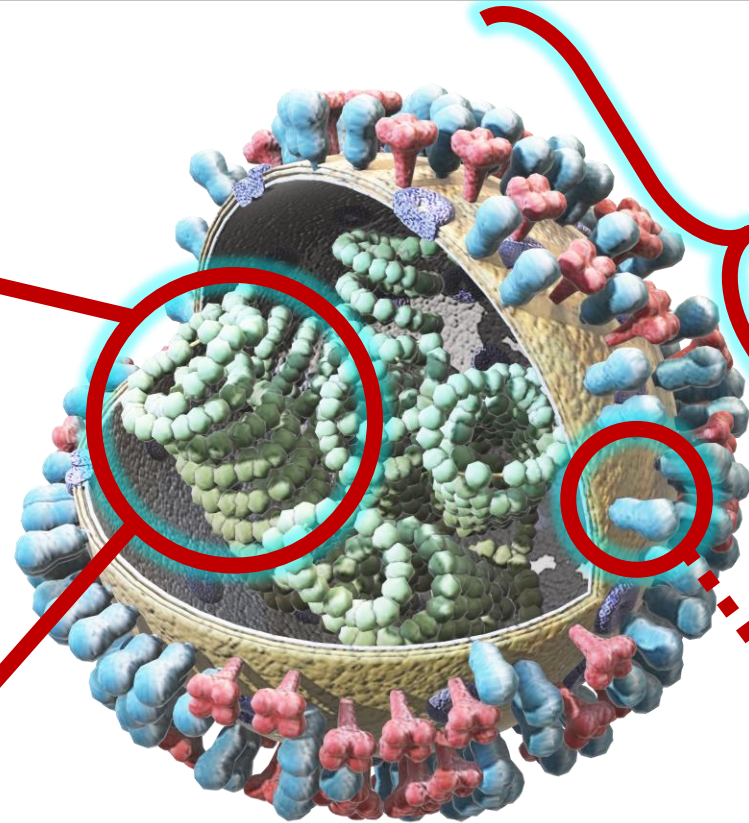
## mRNA vaccine

- **Fragment of RNA** coding spike protein
- RNA wrapped by **PolyEthylene Glycol**
- **Human muscle cells produce S protein**



## Viral vector vaccine

- S protein coding sequence **embedded in a harmless virus**
- **Human muscle cells produce S protein**



## Inactivated vaccine

- **The virus itself** cultured, inactivated and destroyed with chemicals
- **Contains S protein**



## Protein-based vaccine

- Produce S protein by **genetically recombinant plant virus**



# 1. Classification of currently approved COVID vaccines

Class	Pharma	Code name	Dosing	Countries approved/EUA	
mRNA	Pfizer-BioNTech /US	BNT162b2	0, 21d	US, EUs, UK, JP, Israel, ...> 50	Total uptake all over the world: <b>2.02 billion</b> doses as of 3 June 2021
	Moderna /US	mRNA-1273	0, 28d	US, EUs, JP, ...> 20	
Viral vector	Oxford-AstraZeneca	ChAdOx1	0, 12w?	UK, EUs, JP, PH, ...> 80	
	Johnson-Johnson /US	Ad26.COV2.S	Single	US, UK, EUs, PH, ...> 20	
	Gamaleya /Russia	Sputnik V	0, 21d	Russia, DRC, PH, ...> 60	
	CanSino /China	Ad5-nCoV	Single	China, Hungary, ... 6	
Inactivated	Sinopharm /China	BBIBP-CorV	0, 21d	China, UAE, Hungary, ...> 30	
	Sinopharm-Wuhan	WIV04/HB02	0, 21d	China, UAE. 2	
	Sinovac / China	CoronaVac	0, 14d	China, TH, Brasil, ...> 20	
	Bharat Biotech /India	BBV152A,B,C	0, 28d	India, PH, Nepal, ... 12	

\*There are some other vaccines approved/EUA in fewer countries including Protein-based vaccine

## 2. COVID Vaccine efficacy/effectiveness

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## 2. Vaccine efficacy in **phase 3 trials** against **symptomatic COVID**

Class	Pharma	Code name	VE	DOI of articles
<b>mRNA</b>	Pfizer-BioNTech /US	BNT162b2	<b>95.0%</b>	10.1056/NEJMoa2034577
	Moderna /US	mRNA-1273	<b>94.1%</b>	10.1056/NEJMoa2035389
<b>Viral vector</b>	Oxford-AstraZeneca	ChAdOx1	<b>70.4%</b>	10.1016/S0140-6736(20)32661-1
	Johnson-Johnson /US	Ad26.COV2.S	<b>66.9%</b>	10.1056/NEJMoa2101544
	Gamaleya /Russia	Sputnik V	<b>91.6%††</b>	10.1016/s0140-6736(21)00234-8
	CanSino /China	Ad5-nCoV	65.28%*	(*Governmental release only)
<b>Inactivated</b>	Sinopharm /China	BBIBP-CorV	78.1%*	(*Governmental release only)
	Sinopharm-Wuhan	WIV04/HB02	<b>72.8%</b>	10.1001/jama.2021.8565
	Sinovac / China	CoronaVac	50.65%†	(†Pharma press release only)
	Bharat Biotech /India	BBV152A,B,C	78%†	(†Pharma press release only)

†† just before the 2<sup>nd</sup> shot

## 2. Vaccine efficacy in **phase 3 trials** against **symptomatic COVID**

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**mRNA** vaccines **fairly** reduce **symptomatic COVID**

- Approximately **95%**

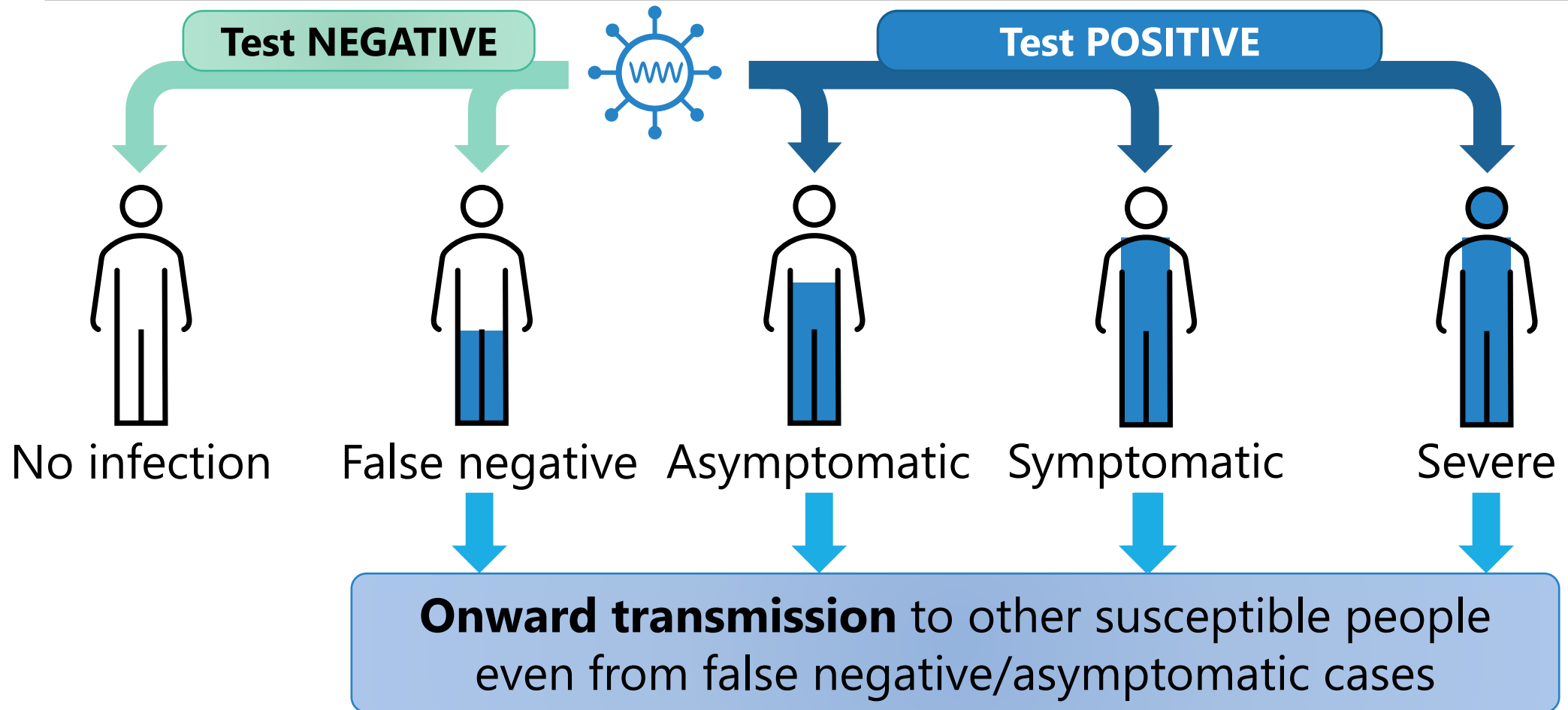
**Viral vector** vaccines **moderately** reduce **symptomatic COVID**

- Ranging **65 to 90%**

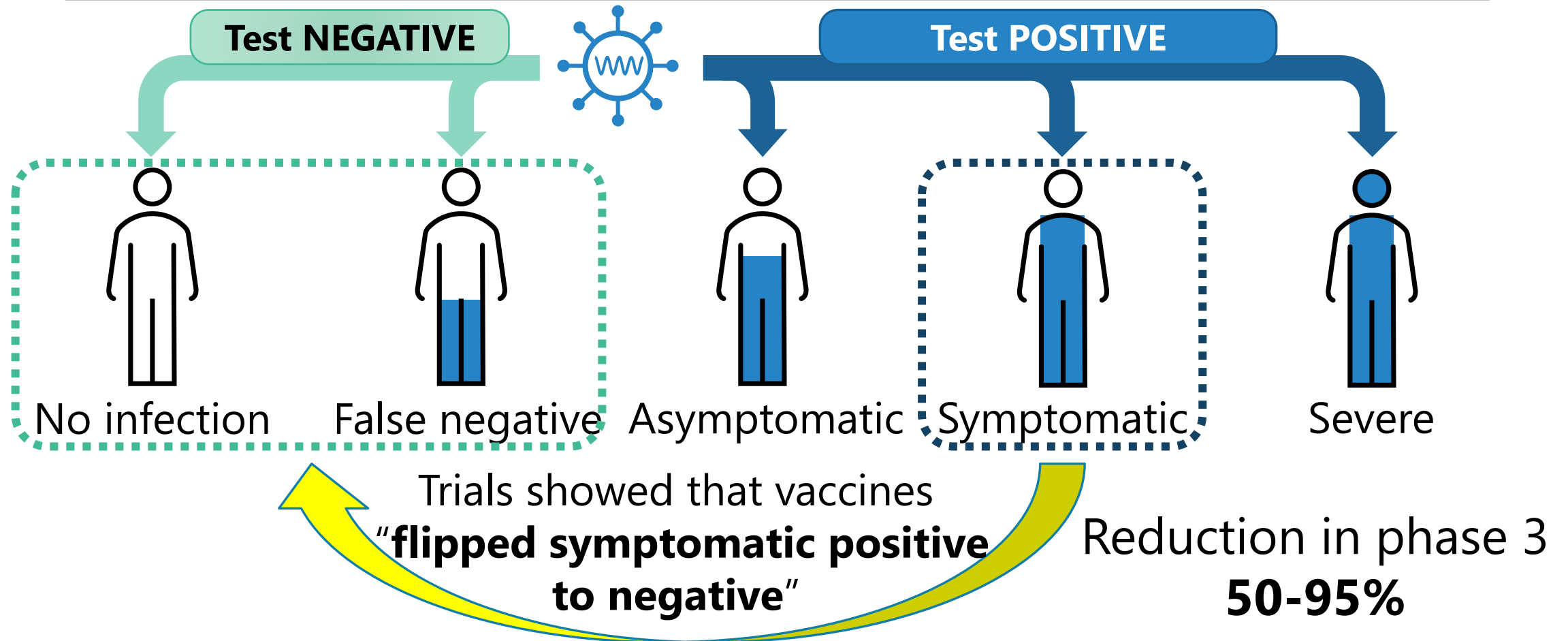
**Inactivated** vaccines **mildly** reduce **symptomatic COVID**

- Ranging **50 to 80%**

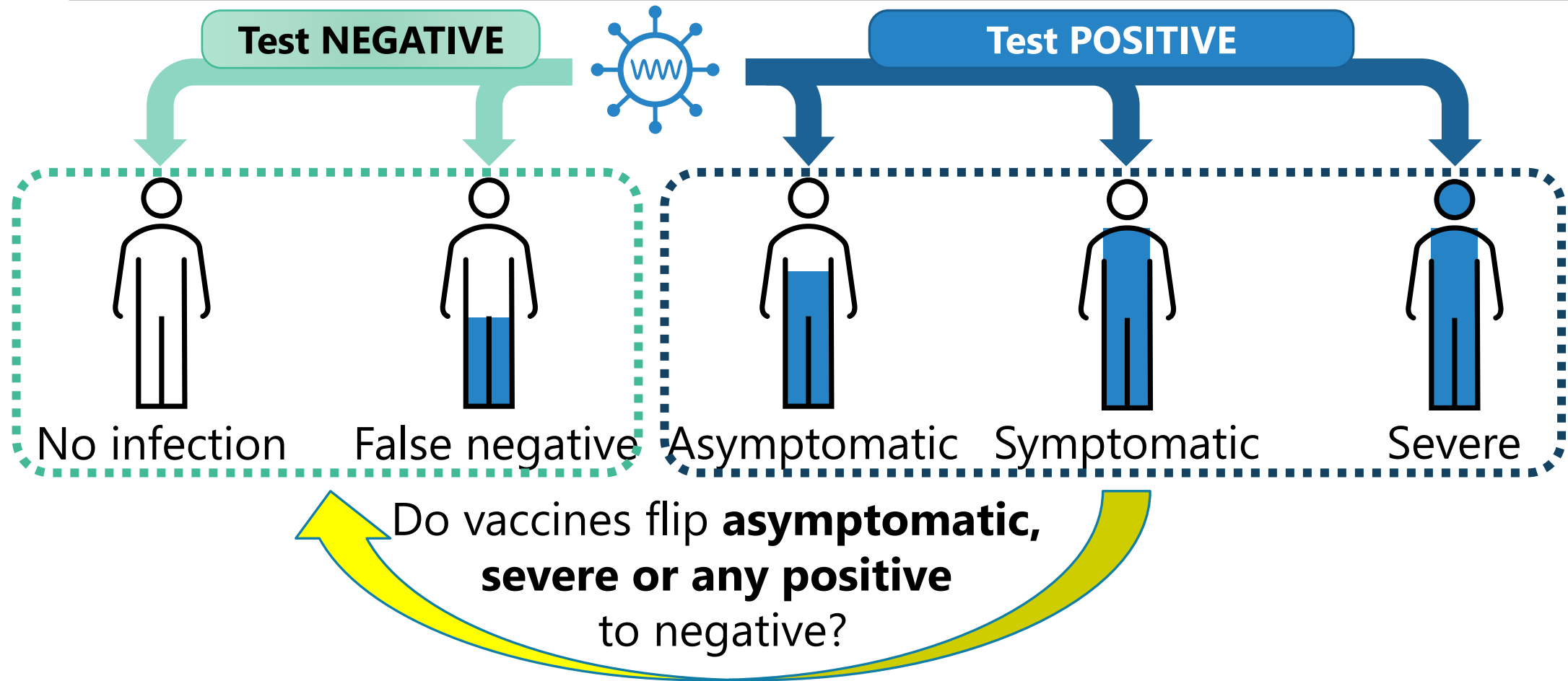
## 2. What happens on individuals after exposure to SARS-CoV-2



## 2. Vaccines reduce **symptomatic** COVID - means “flipping positive to negative”



## 2. Do vaccines reduce other form of COVID positivity **in real world**?





Again

## 2. Vaccine efficacy in **phase 3 trials** against **symptomatic COVID**

Class	Pharma	Code name	VE	DOI of articles
<b>mRNA</b>	Pfizer-BioNTech /US	BNT162b2	<b>95.0%</b>	10.1056/NEJMoa2034577
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	Johnson-Johnson /US	Ad26.COV2.S	<b>66.9%</b>	10.1056/NEJMoa2101544
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<b>Inactivated</b>	Sinopharm /China	BBIBP-CorV	78.1%*	(*Governmental release only)
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	Bharat Biotech /India	BBV152A,B,C	78%†	(†Pharma press release only)

†† just before the 2<sup>nd</sup> shot

## 2. Vaccine effectiveness in real world being established only in 3 so far ....

Class	Pharma	Code name	VE	DOI of articles
mRNA	<b>Pfizer-BioNTech</b> /US	<b>BNT162b2</b>	<b>95.0%</b>	10.1056/NEJMoa2034577
	<b>Moderna</b> /US	<b>mRNA-1273</b>	<b>94.1%</b>	10.1056/NEJMoa2035389
Viral vector	<b>Oxford-AstraZeneca</b>	<b>ChAdOx1</b>	<b>70.4%</b>	10.1016/S0140-6736(20)32661-1
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	Sinovac / China	CoronaVac	50.65%†	(†Pharma press release only)
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†† just before the 2<sup>nd</sup> shot

## 2. Vaccine effectiveness in real world

### – Pfizer & Moderna mRNA vaccines

DOI	Published	Country	Research design	Vaccines	Samples	Symptomatic	Hospitalized	Severe	Asymptomatic	Any
10.1056/NEJMoa2101765	Feb.	Israel	Historical cohort	<b>Pfizer</b>	1.2 million citizens	<b>92</b>	<b>87</b>	<b>92</b>	<b>90</b>	—
10.1093/cid/ciab229	Mar.	US	Historical cohort	<b>Pfizer &amp; Moderna</b>	39,156 patients screened before procedures	—	—	—	<b>80</b>	—
10.15585/mmwr.mm7013e3	Mar.	US	Prospective cohort	<b>Pfizer &amp; Moderna</b>	3,950 healthcare workers	—	—	—	—	<b>90</b>
10.1016/S0140-6736(21)00790-X	Apr.	UK	Prospective cohort	<b>Pfizer</b>	23,324 HCWs				—	<b>86</b>
10.1016/S0140-6736(21)00947-8	May	Israel	Historical cohort	<b>Pfizer</b>	6.54 million citizens	<b>97.0</b>	<b>97.2</b>	<b>97.5</b>	<b>91.5</b>	<b>95.3</b>

**mRNA vaccines** reduce (flip positive to negative) to the degree of **approximately 90%**

## 2. Vaccine effectiveness in real world

### – Oxford viral vector vaccine

2 doses	DOI	Publi shed	Country	Research design	Doses	Samples	Sympto matic	Hospita lized	Severe	Asympt omatic	Any	
	10.1016/S0140-6736(21)00432-3	Mar.	UK	After phase 3 trial	Two	Trial participants 17,178	63.1	—	—	NS	49.5	
Single dose	DOI	Publi shed	Country	Research design	Samples	Outcome	7-13 days	14-20 days	21-27 days	28-34 days	35-41 days	42+ days
	10.2139/ssrn.3789264	Feb.	UK	Prospective cohort	5.4 million citizens	Hospitalized	70	74	84	94	NA 51 vs 0	NA 1 vs 0
	DOI	Publi shed	Country	Research design	Samples	Outcome	22-30 days	31-60 days	61-90 days	22-90 days total	91-120 days	
	10.1016/S0140-6736(21)00432-3	Mar.	UK	After phase 3 trial	17,178 trial participant s	Symptomatic	76.7	72.8	78.3	76.0	NS	
						Asymptomatic	NS	NS	NS	NS	NS	
						Any	62.3	56.3	79.4	63.9	NS	

**2 doses of Oxford** vaccines reduce (flips positive to negative) to the degree of **50 to 60%**  
**Single dose of Oxford** vaccine keeps its effectiveness **3 months at the longest**

## 2. Vaccine effectiveness in real world – against variants

WHO label	Pango lineage	So called...	DOI	Study design	Pfizer	Moderna	Oxford
Alpha	B.1.1.7	UK stain	10.1056/NEJMc2104974	Test negative case control	<b>Any: 89.5 Severe: 100</b>	—	—
			10.1101/2021.05.22.21257658	Test negative case control	<b>Any: 93.4</b>	—	<b>Any: 66.1</b>
Beta	B.1.351	South Africa strain	10.1056/NEJMoa2102214	RCT	—	—	<b>Not effective</b>
			10.1056/NEJMc2104974	Test negative case control	<b>Any: 75.0 Severe: 100</b>	—	—
Gamma	P.1	Brazil stain	(No true endpoint study so far)	—	—	—	—
Delta	B.1.617.2	India strain	10.1101/2021.05.22.21257658	Test negative case control	<b>Any: 87.9</b>	—	<b>Any: 59.8</b>

**Against variants, Pfizer is fairly effective, Oxford moderately, Moderna unknown**



## 2. **mRNA** and **Oxford** vaccines reduce any COVID positivity **in real world**

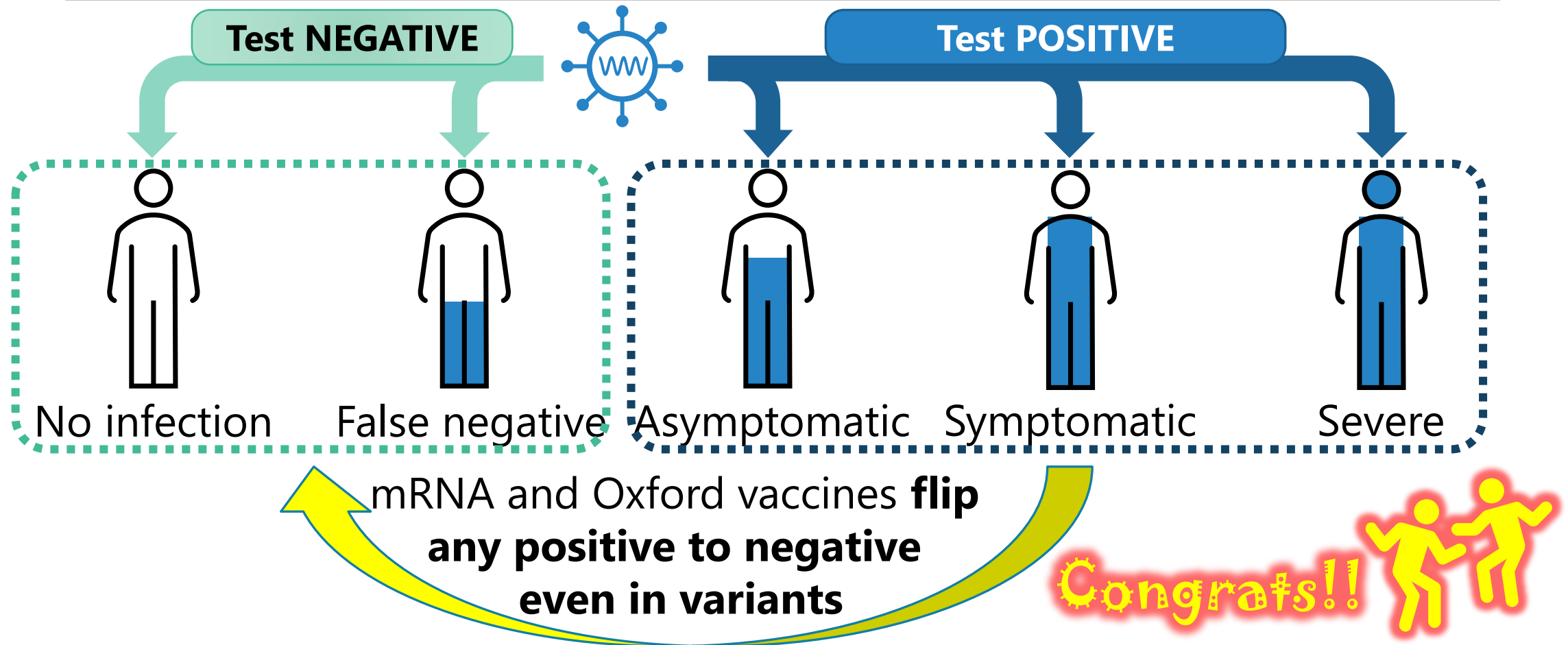
### mRNA vaccines reduce any COVID

- Original strain  $\approx 90\%$
- Alpha, Beta, Delta variants  $\approx 75$  to  $90\%$

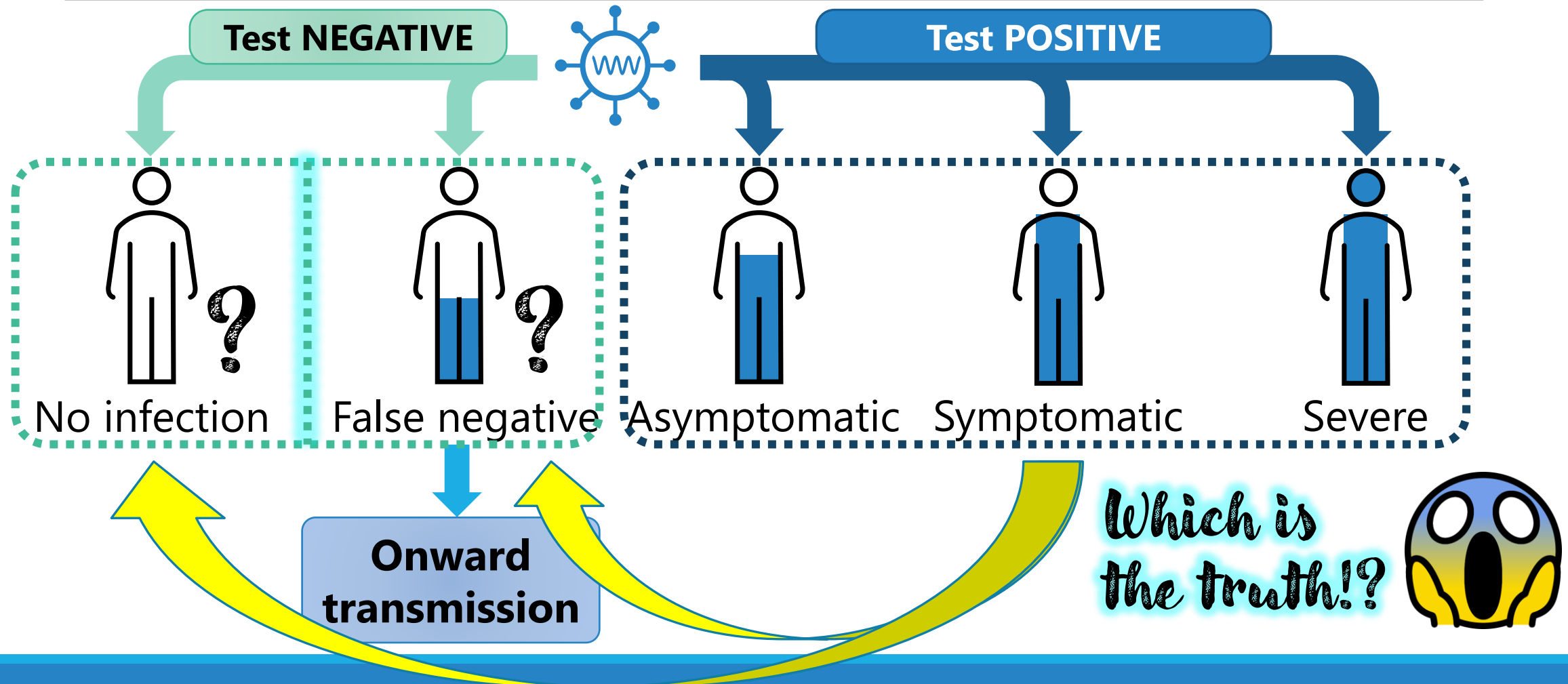
### Oxford vaccine reduces any COVID

- Original stain  $\approx 50$  to  $60\%$
- Single dose  $\approx 70\%$  up to 3 months
- Alpha, Delta variants  $\approx 60\%$

## 2. mRNA and Oxford vaccines reduce any COVID positivity in real world



## 2. But .... How about **False negativity**? Do the vaccinated **still transmit COVID**?



## 2. Proof of “truly no COVID” is *probatio diabolica* (devil’s proof)

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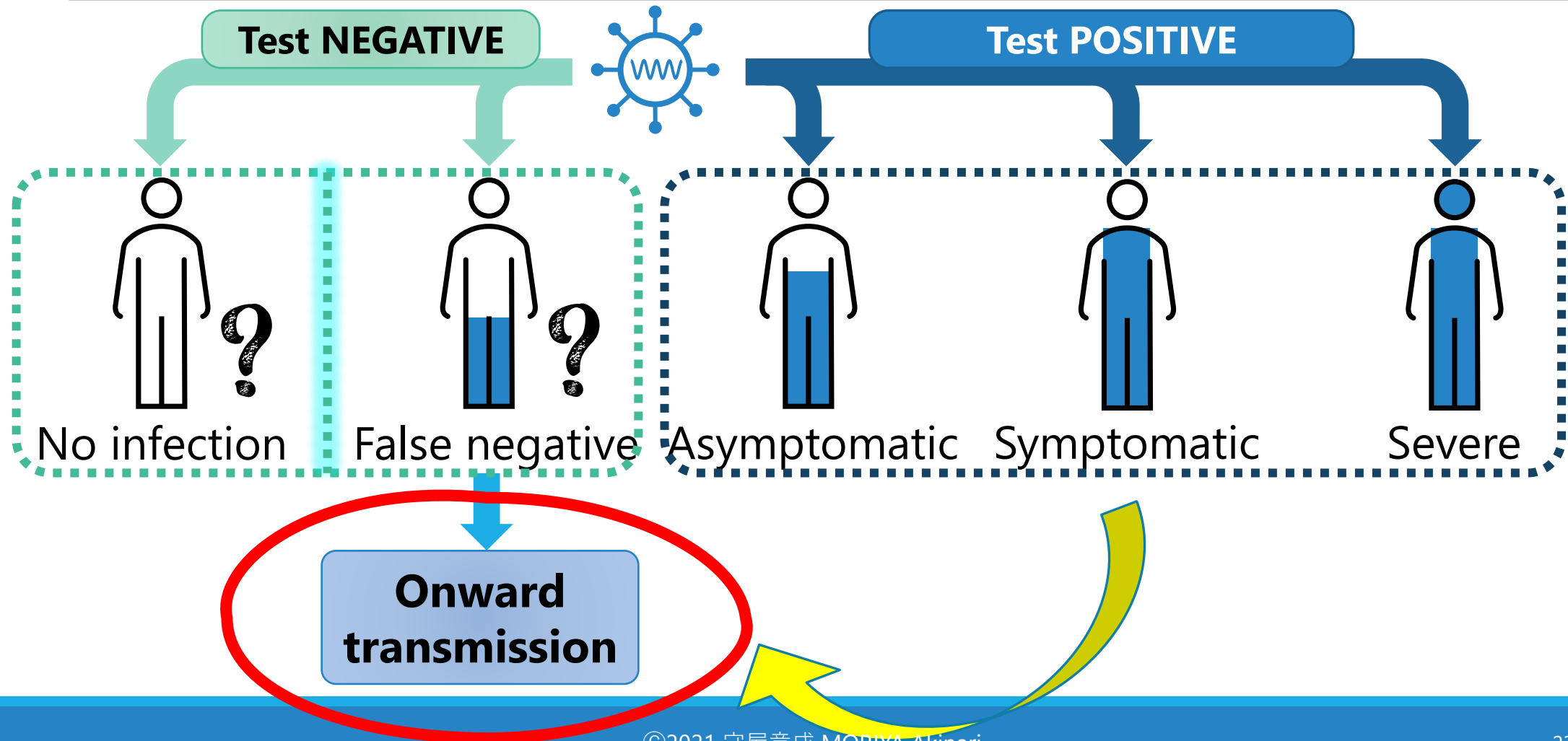
Any COVID tests are quite **less sensitive**

- Negative result cannot exclude infection

Alternative is proof of **reduction of onward transmission**

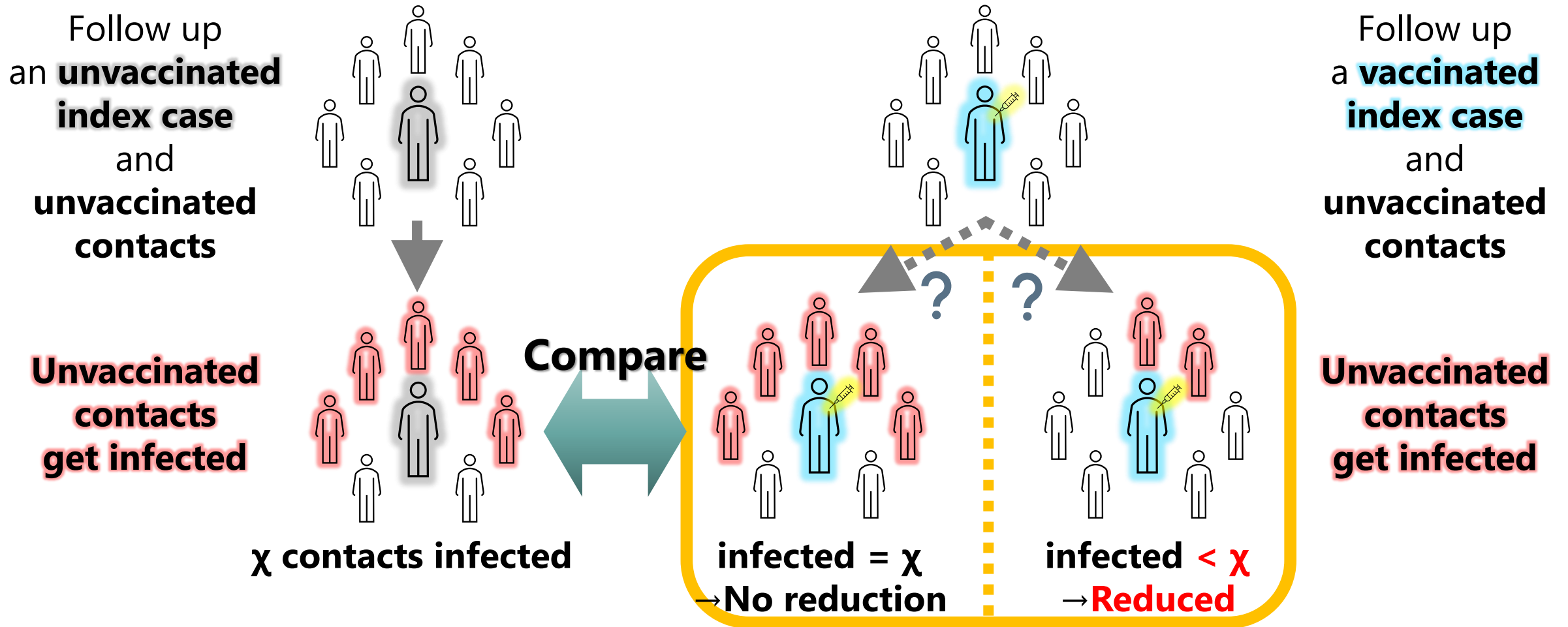
- If onward transmission is also reduced, it indirectly proves true negative
  - ... at least substantially low viral load enough to stop transmission

## 2. Let's look into **onward transmission** from **vaccinated people**

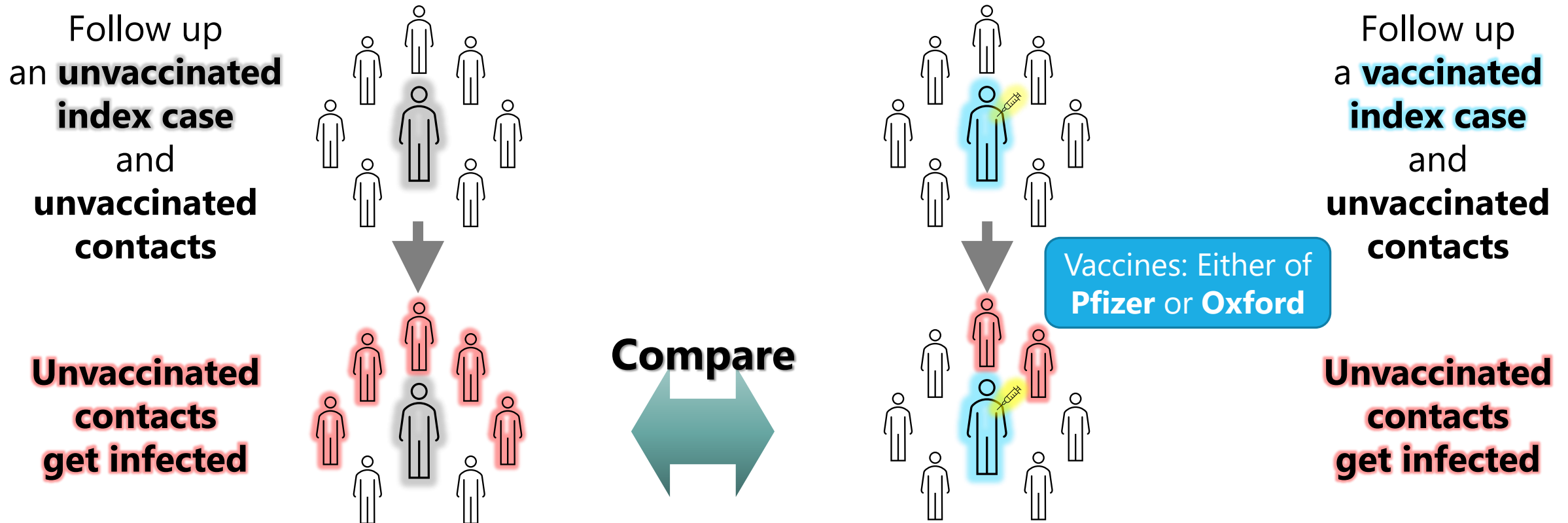




## 2. How to investigate reduction of onward transmission

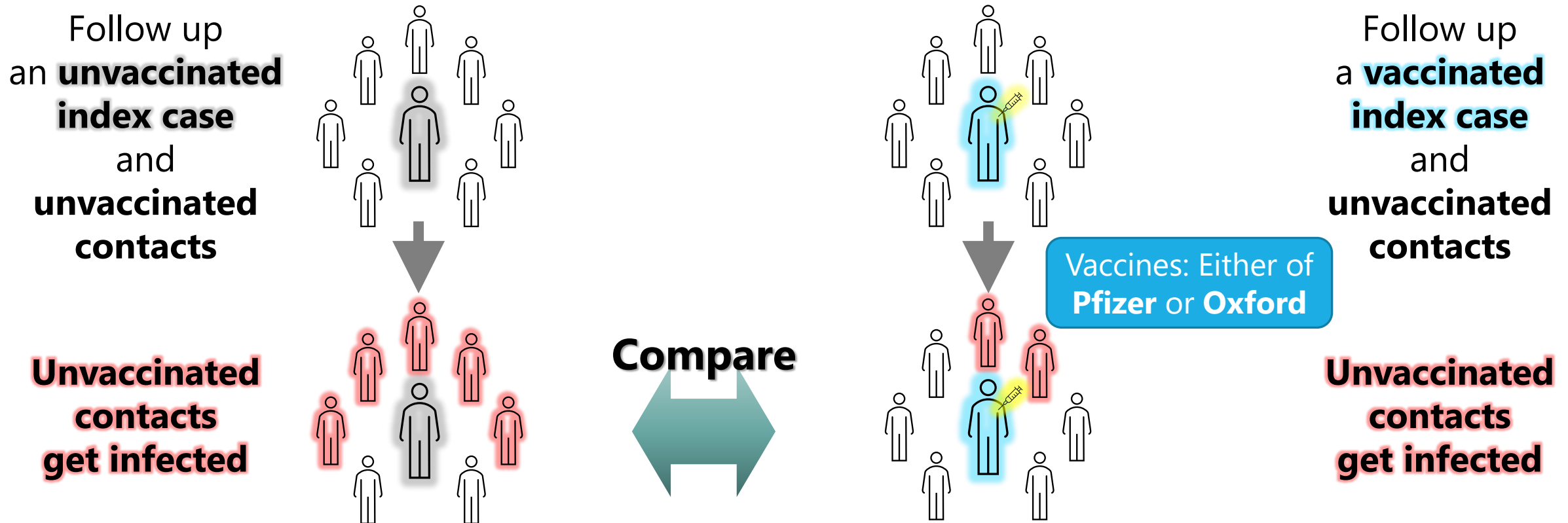


## 2. Study from Scotland, UK - Vaccinated HCWs and unvaccinated household



Hazard ratio of any **COVID** in unvaccinated contacts of **vaccinated** index cases compared to unvaccinated contacts of **unvaccinated** index cases was **0.46-0.50**

## 2. Study from England, UK - Vaccinated citizens and unvaccinated household



**Odds ratio** of any **COVID** in unvaccinated contacts of **vaccinated** index cases compared to unvaccinated contacts of **unvaccinated** index cases was **0.43-0.67**

## 2. Pfizer and Oxford vaccines **reduce onward transmission**

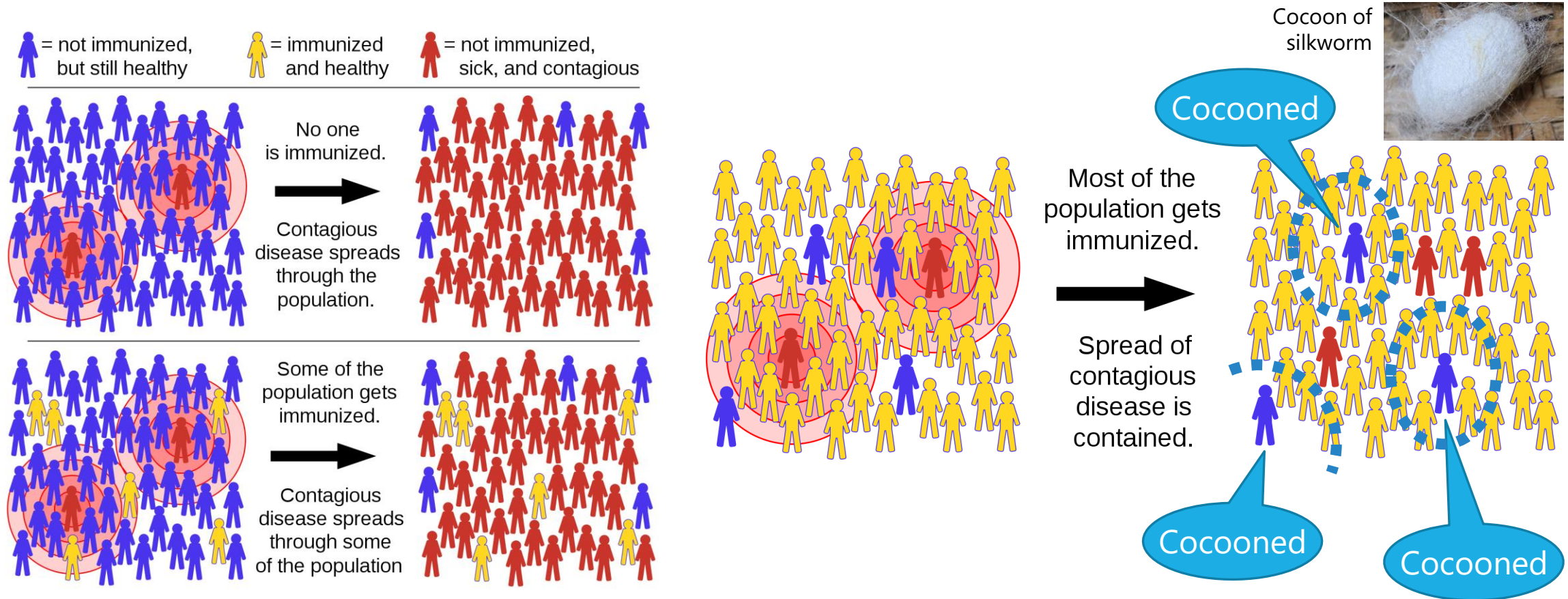
Pfizer and Oxford vaccines **reduce onward transmission**  $\approx 50\%$

- Hereat, please ignore the precise conversions of OR/HR to RR ...
- Reduction of onward transmission leads to **cocooning effect**

It suggests that the vaccines **make vaccinees truly free from infection** to a certain extent

- "A certain extent" should be at least  $\approx 50\%$ 
  - Behavior of unvaccinated contact could be heterogenous and cannot adjust
- "A certain extent" might be around 90%, same as reduction of positivity

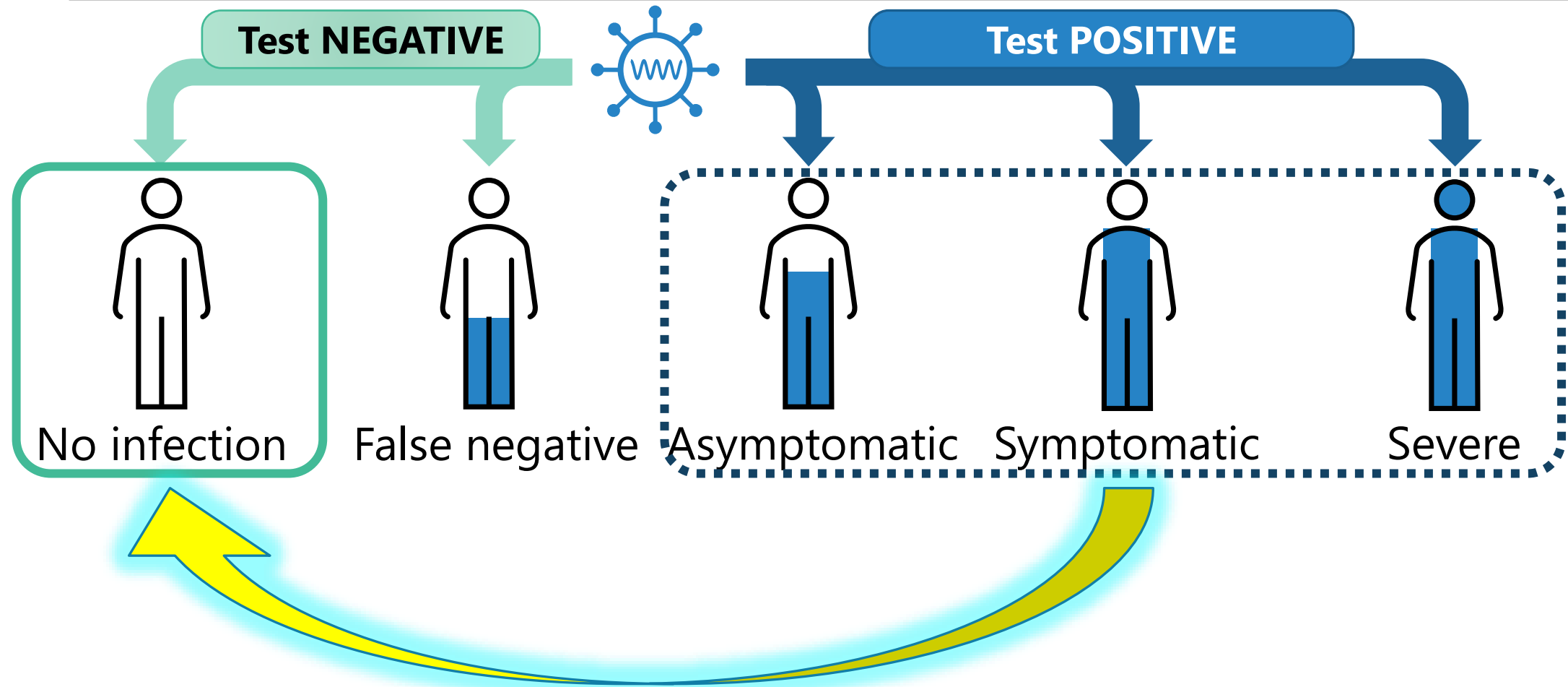
## 2. Pfizer and Oxford vaccines showed **cocooning effect** – **herd immunity**



(CC BY-SA 4.0; Adapted from Mediawiki)



## 2. mRNA and viral vector vaccines **truly prevent infection!** Congrats!!



# 3. Reactogenicity and Anaphylaxis

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### 3. Reactogenicity is a subset of **natural reactions** to vaccination

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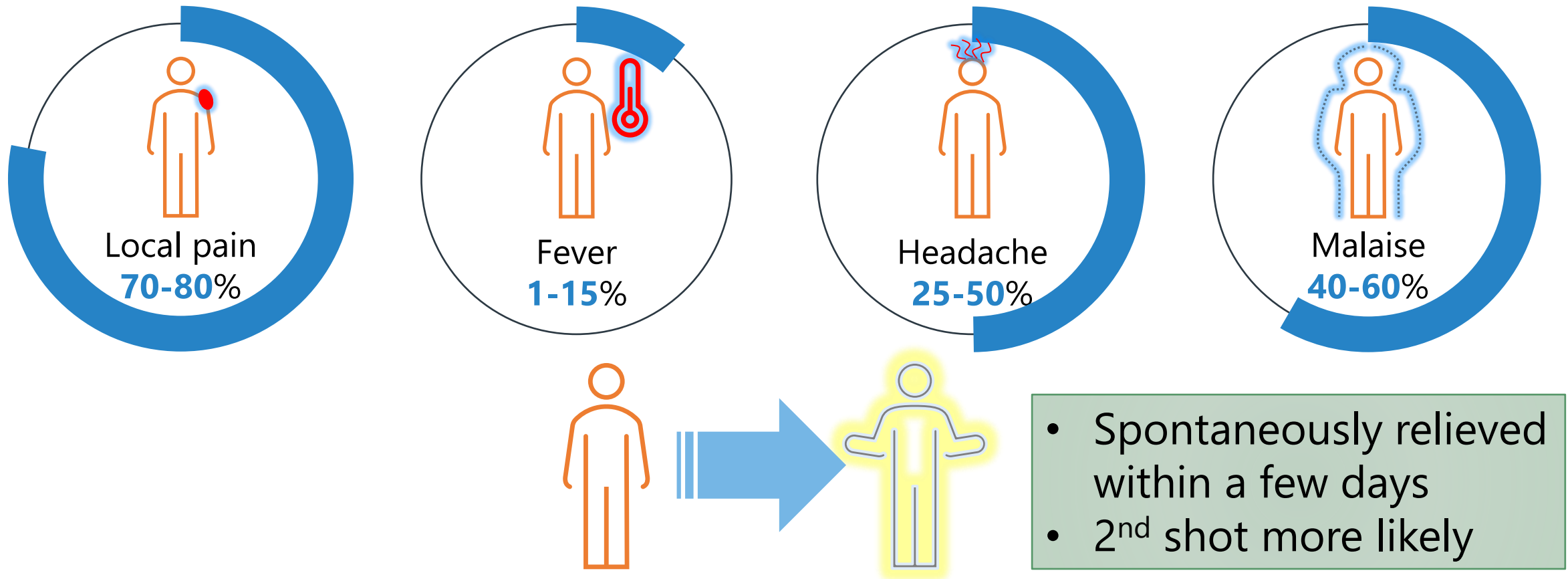
“Reactogenicity is a subset of reactions that occur soon after vaccination, physical manifestation of the **inflammatory response to vaccination**”

- DOI: 10.1038/s41541-019-0132-6

#### Local symptoms and systemic symptoms

- Pain, redness, swelling, induration, regional lymphadenopathy, etc.
- Fever, myalgia, arthralgia, headache, rash, etc.
- Natural and anticipated; even if no reaction, vaccine is definitely working! No worry!

### 3. Reactogenicity of COVID vaccines



# 3. Delayed local hypersensitivity skin reactions by Moderna vaccine

**Almost specific to Moderna vaccine**

**Erythematous, relatively demarcated, pinky to red, large macule**

Appear median **7-8 days after** each dose

- Range 2-14 days
- **After acute reactogenicity**

**Spontaneously resolve** in median **3-6 days**

- Range 1-21 days

Pathology: Delayed or T-cell mediated hypersensitivity reaction

**NO CONTRAINDICATION** for the 2<sup>nd</sup> dose

- More likely in 1<sup>st</sup> dose; can also occur in 2<sup>nd</sup>



“Moderna arm”

DOI:10.1056/NEJMc2102131  
10.1016/j.jaad.2021.03.092  
10.1001/jamadermatol.2021.1214

### 3. Anaphylaxis due to COVID vaccines

DOI	Vaccines	Incidence	Potential allergen
10.1001/jama.2021.1967	Pfizer	4.7 in 1 million vaccinations	Polyethylene glycol (PEG)
	Moderna	2.5 in 1 million vaccinations	Polyethylene glycol (PEG)
(not well published)	Oxford	(unknown well)	Polysorbate 80
(not well published)	Other COVID vaccines	(unknown well)	—
10.1016/j.jaci.2015.07.048	Inactivated influenza	1.3 in 1 million vaccinations	Egg proteins

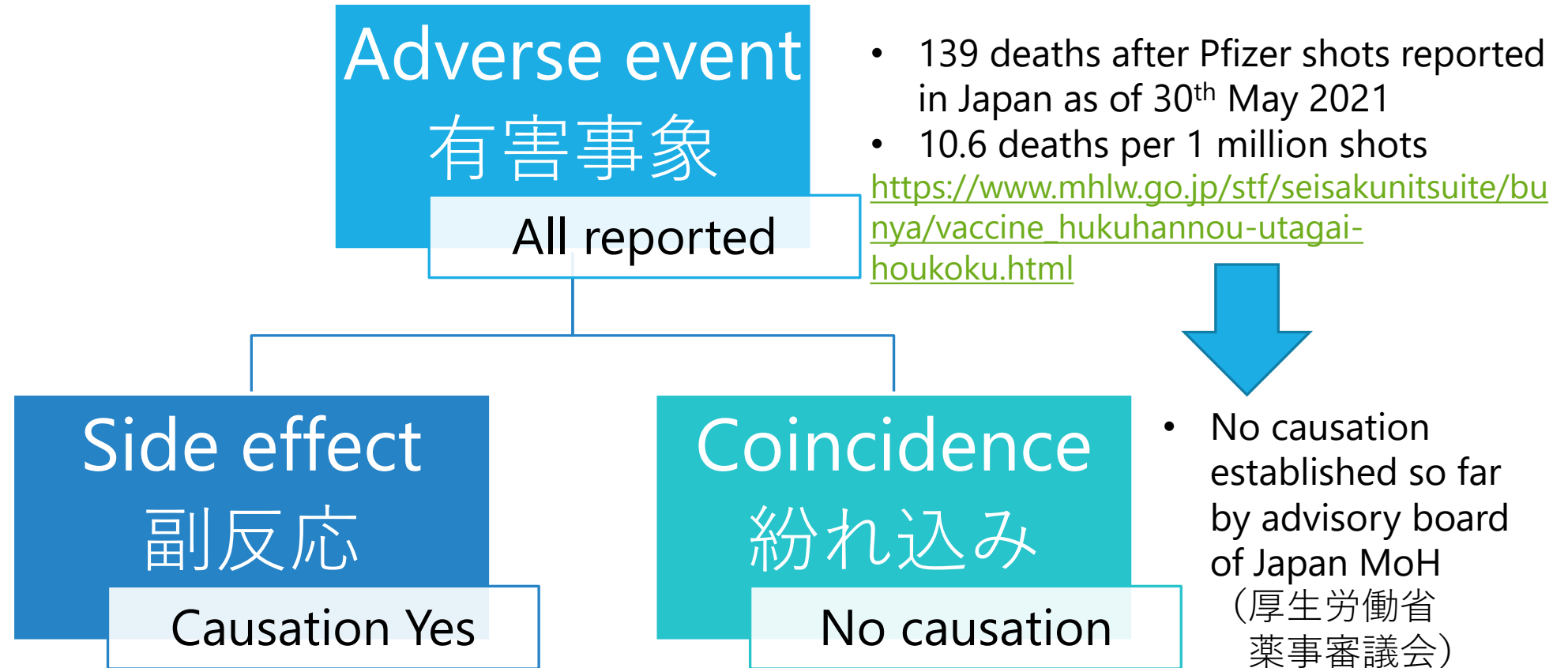
- **Younger females** are much more prone to anaphylaxis due to mRNA vaccines than others
  - **PEG** frequently contained **in cosmetics** may be the reason, but **not yet established**
- Anaphylaxis was more frequent in earlier HCWs period of vaccination campaign – younger females?



# 4. Unexpected severe adverse events/ how to interpret them

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## 4. Clearly distinguish three factors



# 4. Vaccine-induced Thrombotic Thrombocytopenia (**VITT**) – viral vector

DOI	Vaccine	Manifestations	Cases (deaths)	Demography	Timing
10.1056/NEJ Moa2104840	Oxford	Almost all: • <b>Cerebral venous sinus thrombosis</b> • Subsequent <b>thrombocytopenia</b> • Platelet <b>10,000 – 127,000</b> • <b>Antibody to platelet factor 4 – heparin complex</b> positive	11 (5)	22-49 y/o <b>9 of 11 female</b>	5-16 days after the 1 <sup>st</sup>
10.1056/NEJ Moa2104882	Oxford		5 (2)	32-54 y/o <b>4 of 5 female</b>	7-10 days after the 1 <sup>st</sup>
10.1056/NEJ Moa2105385	Oxford		23 (7)	21-77 y/o <b>14 of 23 female</b>	6-24 days after the 1 <sup>st</sup>
10.1001/jama.2021.7517	Johnson Johnson		12 (3)	18< <60 (unrevealed) <b>All female</b>	6-15 days after single

- Only associated with **viral vector vaccines**; no relevant report with mRNA vaccines
- Etiology **not yet established** including production of **PF4-heparin complex antibody**
- Incidence  $\approx$  **1-4 : 100,000 vaccinations**  $\Leftrightarrow$  CVST in general population **0.22-1.57 : 100,000**

## 4. Do mRNA vaccines have unexpected severe adverse events?

**Immune thrombocytopenic purpura** and **Bell's palsy** suggested, but **seems unassociated so far**

- **ITP** - DOI: 10.1002/ajh.26132; **Bell's palsy** - DOI: 10.1001/jamainternmed.2021.2219

mRNA vaccines have been shot at least **0.5 billion** worldwide;  
Any extremely rare undiscovered AE would arise hereafter?

- Probability that "AE of 1 in 10 million **never occurs** among 0.5 billion shots"  
$$= \left(1 - \frac{1}{10 \text{ million}}\right)^{0.5 \text{ billion}} = 1.93 \times 10^{-22} \dots \text{extraordinarily improbable}$$
- mRNA vaccines **would have no unexpected adverse events** so far and hereafter
- If any, unexpected adverse events **in specific subpopulations** would be uncovered

# 4. Are mRNA vaccines associated with myocarditis in adolescent?

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I've just got the information a couple of hours before this presentation

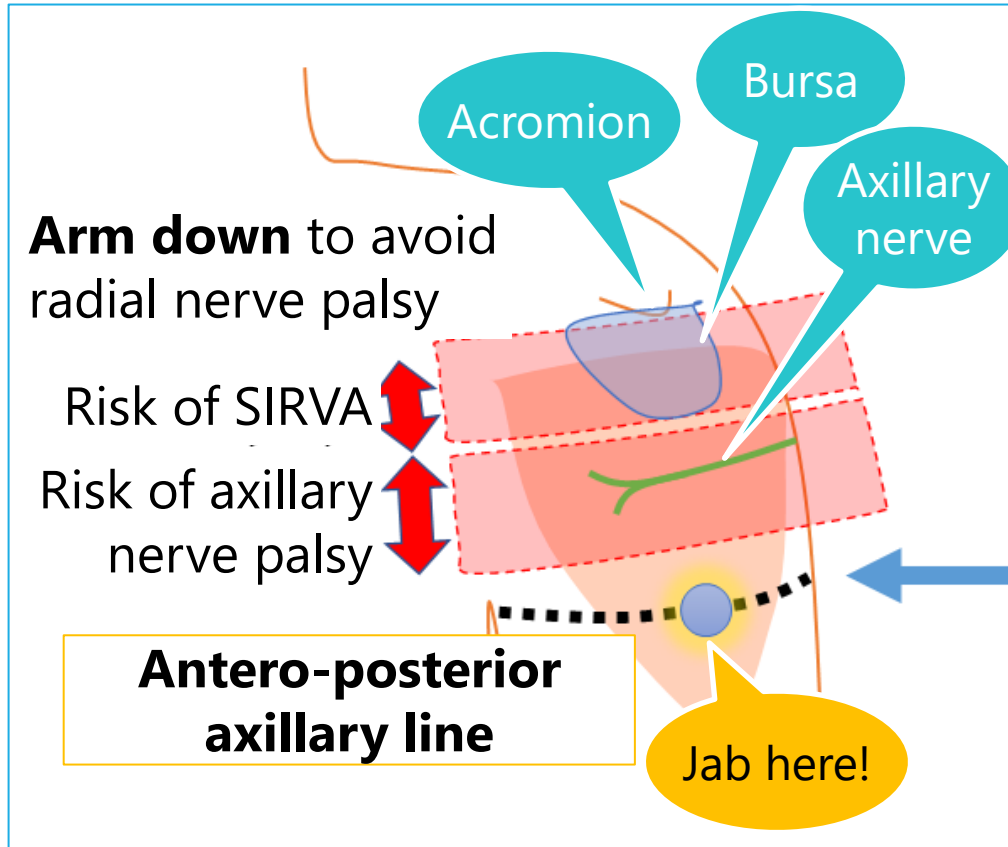
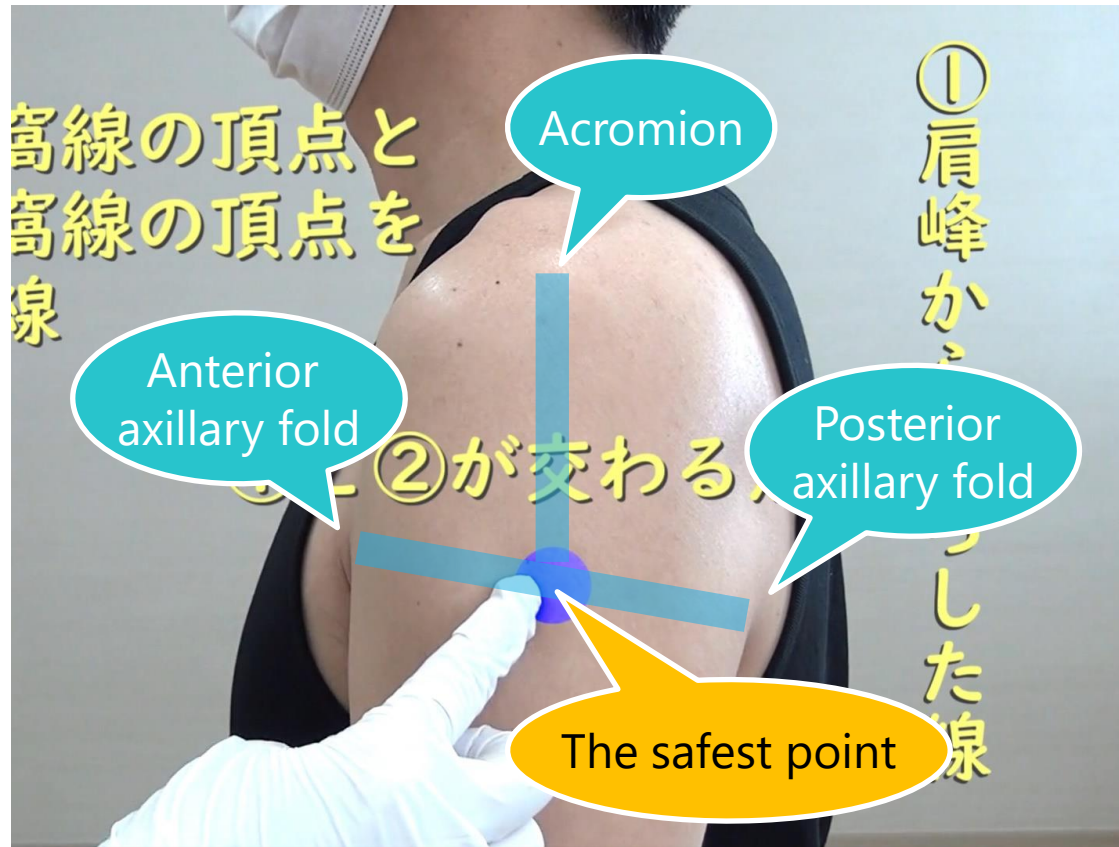
- Couldn't have enough time to investigate details. Sorry...

US-CDC announcement on 27<sup>th</sup> May 2021

<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/myocarditis.html>

- Since April 2021, reports of myocarditis and pericarditis after mRNA vaccines those older than 16 y/o are increasing
- Currently CDC is gathering further information, but has not determined an association with mRNA vaccines and the conditions
- CDC does not think the US should suspend mRNA vaccines to adolescents or young adults

# 4. Avoid SIRVA\* and radial/axillary nerve palsy at deltoid injection!



The video created and authorized by  
Japan Primary Care Association

<https://www.youtube.com/watch?v=tA96CA6f1v8>

\*SIRVA = Shoulder Injury Related to Vaccine Administration

# 4. References for our proposal of new deltoid injection site

DOI	DOI
10.1080/21645515.2017.1334747	10.1080/21645515.2019.1646576
10.1016/j.vaccine.2010.10.005	10.5630/jans.34.36
10.3122/jabfm.2012.06.110334	Bancsi. Can Fam Physician. 2019;65(1):40-42
10.1177/2165079919875161	Szari. Fed Pract. 2019;36(8):380-384.
10.1016/j.vaccine.2017.07.055	Beredjiklian. Pract Neurol. 2012;(October):14-16
10.1016/j.vaccine.2019.11.032	Nakatani. Mem Heal Sci Med Kanazawa Univ. 2004;24:27-31
10.17085/apm.2017.12.2.103	
10.1080/21645515.2015.1017694	Immunisation Handbook. 2020. MoH New Zealand pp.31-74
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Great thanks to **Dr. Nakanishi** in Nara Medical University, an orthopedist who has advocated it and supervised us

# 5. Considerations for specific subpopulations

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# 5. Considerations for specific subpopulations

## Safety and/or effectiveness being established

DOI: 10.1001/jama.2021.7563  
DOI: 10.1056/NEJMoa2104983

- Pregnant/breastfeeding women – no increase of AE observed
- Children over 12 years old – safe and effective US and Japan has already approved
- The oldest old (>85 years old) - safe Many evidences DOI: 10.1016/j.eclinm.2021.100914
- Previously COVID infection – recommended, reactogenicity may decrease in 2<sup>nd</sup>

## Safety and/or effectiveness not enough

- Immunocompromised patients – may less effective DOI: 10.1053/j.ajkd.2021.05.004
- Cancer patients under chemo/radiotherapy – may cause specific reaction DOI: 10.1038/s41591-021-01387-6

# 5. Dedicated communication needed in vaccination for subpopulations

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## For pregnant and breastfeeding women

- “Do not easily link any pregnancy- or breastfeeding-related adverse events after your shots”
- “Have you enough communicated with each of stakeholders including your partner (husband), your parents and his parents?”

## For immunocompromised or cancer patients

- Balancing matters between potential high COVID mortality, potential low vaccine effectiveness, potential worsening of the disease and potential unknown adverse effect
- Encourage to communicate and discuss with doctors in charge of the diseases

# 6. Will COVID vaccines make us free?

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# 6. Let's discuss whether vaccination will make us free or not

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## Medical point of view?

- How safe are vaccinated people?

## Social point of view?

- Is "first come, first freed" ethical?

## To accelerate vaccine uptake?

- Is incentivizing less interested people effective?